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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,432	07/20/2001	Jacob Waugh	13720-105065US1	2657
65989	7590	10/03/2007		
KING & SPALDING 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036-4003			EXAMINER SCHNIZER, RICHARD A	
			ART UNIT 1635	PAPER NUMBER
			NOTIFICATION DATE 10/03/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

<p align="center">Office Action Summary</p>	Application No. 09/910,432	Applicant(s) WAUGH ET AL.	
	Examiner Richard Schnizer, Ph. D.	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-89 is/are pending in the application.
- 4a) Of the above claim(s) 41-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40 and 85 is/are rejected.
- 7) ☒ Claim(s) 86-89 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

An amendment was received and entered on 8/28/07.

Claims 90-137 were canceled.

Claims 40-89 remain pending.

Applicant has elected for examination the species of a non-covalent association complex of a positively charged backbone polymer having positively charged branching groups of the formula $(\text{gly})_p\text{-RGRDDRRQRRR-(gly)}_q$ (SEQ ID NO:19), a negatively charged backbone comprising a plurality of attached targeting moieties, and a negatively-charged backbone having a plurality of attached BOTOX molecules. This species was found to be free of the art. As stated in the restriction requirement of 5/19/04, upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

Currently pending claims 40 and 85 are generic claims.

Claims 41-84 are objected to because they are drawn to non-elected subject matter.

Applicant traverses this objection and argues that "claims 41-84 and 86-89 fall within the elected species (ii/v)" and should be examined. This is persuasive with respect to claims 86-89, but unpersuasive with respect to claims 41-84. The elected species was a non-covalent association complex of a positively charged backbone polymer having positively charged branching groups of the formula $(\text{gly})_p\text{-RGRDDRRQRRR-(gly)}_q$ (SEQ ID NO:19), a negatively charged backbone comprising a

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plurality of attached targeting moieties, and a negatively-charged backbone having a plurality of attached BOTOX molecules, i.e. instant claim 89. None of claims 41-84 and 86-88 are limited to a positively charged backbone polymer having positively charged branching groups of the formula (gly)_p-RGRDDRRQRRR-(gly)_q (SEQ ID NO:19), and a negatively-charged backbone having a plurality of attached BOTOX molecules, so they are not the same species. As stated in the restriction requirement of 5/19/04, upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. For these reasons claims 41-84 and 86-88 stand withdrawn.

Claims 41 and 85-89 are under consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 40 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al (US 6,680,301).

Berg taught compositions for transferring nucleic acid molecules into the cytosol of cells. In one embodiment, the compositions comprise a polycation such as polylysine, polyarginine or polyethyleneimine complexed to a nucleic acid, and

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photoactivating compounds that are attached to the nucleic acid. The photoactivating compound acts as a targeting agent because it acts to release the nucleic acid into the cell cytosol from an endosomal or lysosomal compartment when excited by light of the appropriate wavelength, and because it targets tumor cells preferentially. See abstract; column 2, line 55 to column 3, line 1; column 7, lines 30-38; column 7, lines 66 to column 8, line 5; and column 8, lines 23-27. The photoactivating compounds belong to a recognized class of therapeutic agents that used in photodynamic therapy, and also appears to be therapeutic in that it seems to mitigate the effect of releasing lysosomal toxins. See column 1, lines 34-52; and column 7, lines 11-20. Because the photoactivating compounds can be used to treat tumors of the skin, they are also considered to be cosmeceutical agents. Berg exemplifies positively charged complexes. See column 13, lines 1-4; column 14, lines 36-43; column 15, lines 29-37; column 16, lines 21-27; and paragraph bridging columns 16 and 17.

So, Berg taught a net positively charged, noncovalent complex of a positively charged backbone and a negatively charged backbone, wherein the negatively charged backbone has at least one attached agent that is a photosensitizing compound. The photosensitizing compound is recognized as both a therapeutic/cosmeceutical compound and a targeting agent. Note that limitations requiring the use of two non-identical negatively charged backbones were deleted by the amendment of 8/17/07.

Berg was silent as to the number of photosensitizing/targeting agents that could be attached to the negatively charged backbone.

The number of photosensitizing/targeting agents that could be attached to the negatively charged backbone is considered to be a result effective variable that is obvious to optimize, because Berg taught that the concentration of photosensitizer is a result-effective variable (see column 7, lines 64-66). Finally, Berg indicates at column 8, lines 31-33 that molecules for delivery can be "linked to... photosensitizers. This implies that more than one photosensitizer can be linked to a nucleic acid that is to be delivered to the cytosol of the cell. Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to attach more than one photosensitizer to the nucleic acid of Berg.

Thus the invention as a whole was prima facie obvious.

Conclusion

No claim is allowed. Claims 86-89 are objected to because they depend from a rejected claim, but would be allowable if rewritten in independent form incorporating all the limitations of the claim(s) from which they depend.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Richard Schnizer, Ph.D.
Primary Examiner
Art Unit 1635